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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,513	03/26/2001	Therese Jourdicr	MBHB00-1282	3546
20306	7590	09/22/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			LI, BAO Q	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/720,513

Applicant(s)

JOURDIER ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/03/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment, paper No. 22, filed 06/28/04. Claim 10 has been amended. Claims 10-15 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claim Rejections - 35 USC § 103***

1. Claims 10-15 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961) under the same ground as stated in the previous Office Action.
2. Applicants traverse the rejection and still argue that the evidence shown by the declaration is persuasive because the examiner during the interview on 09/23/2003 acknowledged the result in the page 19 of the specification as an unexpected result. Thus, the file history and objective evidence on page 19 establish that the results of the instant invention are unexpected.
3. Applicants' argument has been fully considered; however, it is not persuasive. Because the phenomena of inducing a stronger local immune response than the response in the distant place by injection an antigen locally does not seem to be unexpected results. The examiner has already pointed out in the previous Office Action that the data presented on page 19 does not have a control group. In other word, it would be expected if an antigen is injected locally no matter through thigh intramuscularly or through the membrane or skin subcutaneously near the rectogenitourinary system, a better immune response will be first observed near that area than any other distant place, such as subaxillary or axillary lymphnodes. It is well known in the art, when a foreign antigen first appears in the body, it will induce a local inflammation and local immune response first because the regional antigen presenting cell, such as macrophage will

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present the antigen to the local B cells in the germinal center of the lymphocyte. In return the B cell will be activated and produce the antibody locally.

4. Moreover, the prior art as cited by the previous Office Action already teaches that the thigh injection is better than other for induce an immune response for a pathogen. For example, Stities et al. teach that recent studies of injection techniques suggest that the arterolateral thigh or deltoid site is preferable to the buttocks. Groswasser et al. disclose that a better immune response for intramuscular compared with subcutaneous injection has been seen with several vaccines, such as the hepatitis B, rabies and influenza vaccines (See first paragraph on page 400), in which the thigh injection is referred by Dr. Groswasser et al. as the site of quadriceps (See section of materials and methods on page 401). More importantly, Bouvet et al. already point out that a secreting vaccine for inducing protective antibodies is a major interest in the field because the antibodies in secretions can play a key role against the pathogens, which remain in the genital area. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using a method of injecting an immunogenic composition locally near the genital area to product better immune response absence unexpected result.

5. Because the data at page 19 does not have a control group, the applicants cannot approve that the result is an unexpected result, the rejection is still maintained.

### ***Conclusion***

No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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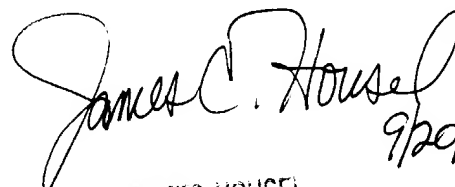
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

09/16/2004

  
9/20/04  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY AND INVENTIONS